

**REMARKS**

Favorable reconsideration of this application is respectfully requested.

Claims 1-9, and 13-24 remain pending in this application; claims 2-9, 13-14, and 20-24 have been amended herein for clarification.

In the Office Action of February 6, 2008, the Examiner: (1) rejected claims 2-9, 13-14, and 20-24 under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; (2) rejected claims 1-6, 8-9, 15-18, 20-22 and 24 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,804,691 to English et al. (hereinafter English); (3) rejected claim 23 under 35 U.S.C. §103(a) as obvious over English in view of U.S. Patent No. 6,339,130 to Bennett et al. (hereinafter Bennett); and (4) rejected claims 1-9, 13-22, and 24 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,057,535 to Lipatova et al. (hereinafter Lipatova) in view of English and U.S. Patent No. 4,388,245 to Ueyanagai et al. (hereinafter Ueyanagai). These rejections are respectfully traversed.

With respect to the rejection of claims 2-9, 13-14, and 20-24 under 35 U.S.C. §112, second paragraph, applicant has amended those claims herein for clarification and respectfully submits these amendments render the rejections moot.

Applicant traverses the rejection of claim 15 as indefinite for the use of the terms "approximating" and "approximated." As set forth in the specification, "The bioabsorbable compounds and compositions described herein are advantageously useful as a surgical adhesive or sealant, for example, for joining portions of body tissue

together....” (See ¶22 of the application as published, U.S. Patent Publication No. 2006/0111537.)

It is respectfully submitted that the terms “approximating” and “approximated” are commonly used in the fastening art, and that one skilled in the art would understand these terms as utilized in claim 15 to mean bringing two tissue surfaces close together so that they may be joined. As previously noted, the American Heritage College Dictionary provides as a definition for “approximate” the following: “To bring near or together.” A copy of this definition is attached hereto as Exhibit A. Moreover, U.S. Patent Nos. 6,894,140 and 6,562,025 both refer to approximating tissue and then uniting tissue. Thus, it is respectfully submitted that the terms “approximate” and “approximating” are definite and the rejection of claim 15 should be withdrawn.

With respect to the rejection of claims 1-6, 8-9, 15-18, 20-22 and 24 under 35 U.S.C. §103(a) as obvious over English, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1.

English provides an adhesive formed by reacting a biodegradable monomer with a polyhydroxy polymerization initiator in the presence of a catalyst and preparing a diisocyanate-terminated prepolymer adhesive by reacting the resulting hydroxyl-terminated polyester with excess aromatic diisocyanate. While the prepolymer may be utilized as a single-component or two-component system, nowhere is there any teaching or suggestion in English of a composition including a bioabsorbable oligomeric

compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. The Examiner asserts, without any support, that the use of excess diisocyanate in forming the single component adhesive necessarily requires both an isocyanate-terminated prepolymer as well as additional diisocyanate monomer.

The Examiner then states that while English fails to teach a polyurethane system that would be a mixture of di- and tri- functional compounds, it would be obvious to combine two compositions to form a third composition. However, claim 1 requires 3 components: a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. Nowhere does English disclose or suggest, nor does the Examiner identify where English purportedly discloses or suggests, these 3 separate components. Without such teaching or suggestion, English cannot render claim 1 obvious, nor claims 2-6, 8-9, 15-18, 21-22 and 24 which depend directly or indirectly from claim 1 and incorporate all of its limitations therein.

With respect to claim 20, English nowhere discloses or suggests a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition. As noted above with respect to claim 1, nowhere does English disclose or suggest applying to a tissue a composition including the 3 separate components, i.e., a bioabsorbable oligomeric compound that is end-capped with an

aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. Without such teaching or suggestion, English cannot render claim 20 obvious.

With respect to the rejection of claim 23 as obvious over English in view of Bennett, claim 23 depends indirectly from claim 1 and incorporates all of its limitations therein. As described above, English does not render claim 1 obvious. Bennett fails to remedy the deficiencies of English, no matter how these references may be combined.

As noted by the Examiner, Bennett specifies that the selection of diisocyanate is important and that certain aromatic diisocyanates should not be employed due to toxicity concerns. Bennett does not disclose a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. Thus, Bennett cannot render obvious the pending claims, and it is respectfully submitted that claim 23 is patentable over English and Bennett, no matter how these references may be combined.

With respect to the rejection of claims 1-9, 13-22 and 24 under 35 U.S.C. §103(a) as obvious over Lipatova in view of English and in view of Ueyanagi, nowhere does Lipatova disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. Nor does Lipatova disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped

with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition as recited in claim 20.

Similarly, nowhere does Lipatova disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and  $\epsilon$ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-

aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene] and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19.

Rather, Lipatova discloses an adhesive including aromatic diisocyanates, macrodiisocyanates of a defined formula, and 2,4,6-tris(dimethylaminomethyl)phenol. Nowhere in Lipatova is there any teaching or suggestion of a trifunctional compound that is end-capped with an aromatic diisocyanate. In fact, as admitted by the Examiner, Lipatova does not disclose bioabsorbable polyesters and trifunctional adducts of the aromatic polyisocyanate. Without such disclosure, Lipatova cannot anticipate or render obvious the pending claims including independent claims 1, 19, and 20. As claims 2-9, 13-18, 21-22 and 24 all depend, directly or indirectly, from claim 1 and incorporate all of its limitations therein, Lipatova similarly cannot render obvious those claims.

English fails to remedy the deficiencies of Lipatova, no matter how these references may be combined. As noted above with respect to claims 1 and 20, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1. In addition, nowhere does English disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound

that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition as recited in claim 20.

Similarly, nowhere does English disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and  $\epsilon$ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-

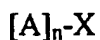
diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19.

As noted above, while English provides an adhesive formed by reacting a biodegradable monomer with a polyhydroxy polymerization initiator in the presence of a catalyst and preparing a diisocyanate-terminated prepolymer adhesive by reacting the resulting hydroxyl-terminated polyester with excess aromatic diisocyanate, nowhere is there any teaching or suggestion in English of a composition or method of applying a composition including the 3 separate components recited in claims 1, 19 and 20.

Uenayagi fails to remedy the deficiencies of Lipatova and English, no matter how these references may be combined. Nowhere does Uenayagi disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate as recited in claim 1.

Similarly, nowhere does Uenayagi disclose or suggest a method which includes applying to tissue a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate, and crosslinking the composition as recited in claim 20.

Moreover, nowhere does Uenayagi disclose or suggest a composition including a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, wherein the bioabsorbable oligomeric compound has the structure:



wherein A is a bioabsorbable group derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, 1,4-dioxane-2-one, 1,3-dioxane-2-one and  $\epsilon$ -caprolactone, n is from about 1 to about 6 and X is a residue from a multifunctional initiator selected from the group consisting of ethylene glycol, diethylene glycol, 1,3-propanediol, 1,4-butanediol, 1,5-pentanediol, 1,6-hexanediol, 1,7-heptanediol, 1,8-octanediol, 1,10-decanediol, 1,12-dodecanediol, 1,2-decanediol, 1,2-dodecanediol, 1,2-hexadecanediol, 3-methyl-1,5-pentanediol, 2-methyl-1,3-propanediol, 2-butyl-2-ethyl-1,3-propanediol, 2-ethyl-3-butyl-1,3-propanediol, 2-ethyl-1,6-hexanediol, glycerol, 1,1,1-trimethylolpropane, neopentyl glycol, pentaerythritol, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, 4-aminobutanols, succinic acid, glutaric acid, adipic acid, suberic acid, sebacic acid, dodecanedioic acid, 2-ethyl-2-methylsuccinic acid, phthalic acid, isophthalic acid, and terephthalic acid; a trifunctional compound that is end-capped with an aromatic diisocyanate, wherein the trifunctional compound is selected from the group consisting of glycerol, 1,1,1-trimethylolpropane, triethanolamine, 1-aminopropanols, 2-aminopropanols, 2-aminobutanols, and 4-aminobutanols; and an aromatic diisocyanate selected from the group consisting of 1,4-diisocyanatobenzene, 1,1'-methylenebis[4-isocyanatobenzene], 2,4-diisocyanato-1-methylbenzene, 1,3-diisocyanato-2-methylbenzene, 1,5-diisocyanatonaphthalene, 1,1'-(1-

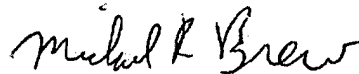
methylethylidene)bis[4-isocyanatobenzene) and 1,3- and 1,4-bis(1-isocyanato-1-methylethyl)benzene, as recited in claim 19.

While Uenayagi discloses processes for preparing modified aliphatic, alicyclic, or araliphatic organic polyisocyanates, which include prepolymers that may be dimers, trimers, tetramers, pentamers, or mixtures thereof, its processes include heating a polyisocyanate having at least two isocyanate groups in the presence of a diisocyanate monomer to form the modified polyisocyanate. Nowhere is there any teaching or suggestion of a composition including the three components recited in claims 1 and 19, namely, a bioabsorbable oligomeric compound that is end-capped with an aromatic diisocyanate, a trifunctional compound that is end-capped with an aromatic diisocyanate, and an aromatic diisocyanate. Moreover, nowhere is there any teaching or suggestion of applying such a composition to tissue as recited in claim 20. Without such teaching or suggestion, Uenayagi fails to remedy the deficiencies of Lipatova and/or English, no matter how these references may be combined. Thus, claims 1-9, 13-22 and 24 are patentable over Lipatova, English, and/or Uenayagi, and withdrawal of this rejection is respectfully requested.

It is believed that the claims of the application as now presented, i.e., claims 1-9, and 13-24, are patentably distinct over the art of record and are in condition for allowance. In the event that the Examiner believes that a telephone conference or a

personal interview may facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. Early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,



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